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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,074	11/24/2003	John Gregory Aceti	0055885-000006	4158

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EXAMINER	
WINAKUR, ERIC FRANK	
ART UNIT	PAPER NUMBER
3768	

NOTIFICATION DATE	DELIVERY MODE
10/03/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/722,074	ACETI ET AL.	
	Examiner	Art Unit	
	Eric F. Winakur	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-80* is/are pending in the application.

4a) Of the above claim(s) *8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/30/04; 8/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species A) a monitoring arrangement including one or more needles and a light source aligned to heat tissue, and B) a monitoring method and arrangement including at least first and second concentration measurement means and activation means for allowing scheduled measurements with the measurement means. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing**

the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

2. During a telephone conversation with Scott Cummings on 17 September 2008 a provisional election was made without traverse to prosecute the invention of species B,

claims 9 - 80. Affirmation of this election must be made by applicant in replying to this Office action. Claim 8 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 20 - 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although the specification (page 16, lines 3 - 6) provides details of timing for performing the measurements, the specification only mentions that the schedule may be pre-established, programmed by a user or medical personnel, or chosen from two or more pre-established timetables. However, there is no teaching of an arrangement that includes a scheduling mode responsive to previously collected measurements, as required in claims 20 - 22. As such, the claims

are drawn to subject matter not in possession of Applicant at the time the application was filed.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 9 - 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The independent claims use the relative phrase “substantially painless” without adequately defining the phrase in the claims, nor does the specification provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since pain and thresholds of pain vary between individuals, the phrase "substantially painless” has a varying meaning. Use of the term “optionally” in the independent claims renders the scope of the claims unclear, as it is uncertain whether the limitations that follow the term are intended to be part of the claimed inventions. With regard to claims 41 and 74, use of the term “of” in the phrase “at least one of" appears to permit a choice of less than all of the elements from the list that follows to be members of the kit, when it appears more likely that Applicant intends at least one of each of the elements to be included in the kit. It is unclear what further limitations are set forth by claims 14, 26, and 53, as the claims from which they depend are drawn to ex vivo measurement, which is generally considered to require that the measurement is performed outside of the host.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 9, 16 - 19, 30, 31, 35 - 37, 41, 42, 46 - 48, 55 - 57, 63 - 65, 68 - 70, 73 - 75, and 78 - 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Simons et al. (USPN 5,971,941 - cited by Applicant). Simons et al. teach an integrated system and method for sampling blood and analytes, in particular glucose concentration is determined. Lancing strips, as illustrated in Figures 1A and 1B and described in the Cartridges and Flat Cartridges sections (see columns 5 - 7) are containted within a cassette in a housing (see Glucometer and columns 12 - 14). The system includes elements to allow the user to set time and other parameters of interest (column 13, ilnes 4 - 31). As for limitations regarding the predetermined time periods and predetermined schedule and schedule mode, any persons needing to use such equipment has a set schedule for taking such readings and then retaking them on a set schedule based upon may parameters, such as what the previous reading was, eating times, etc. Thus all of the claim limitations drawn to scheduling and time periods are inherently met during the use of the system. As for the limitation concerning the kit having instructions, all medical devices come with instructions for their use. With regard to claims 30 and 63, the device of Simons et al. includes buttons and other input elements/switches which are considered to correspond with the claimed “activation means” as set forth. As Simons includes a removable cartridge meeting the limitations of claim 41 ("kit

comprising: at lest one of"), and the details of the device in claim 42 are not further limiting to the cartridge, Simons is considered to meet claim 42 when the cartridge is chosen. With regard to claim 48, without claiming any structure for executing a "program", the phrase "programmed by" is considered to not require implementation on a processor or automatic execution, but rather to be equivalent to "predetermined by", which is met by Simons for the reasons above.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 10 - 15, 32 - 34, 38 - 40, 43 - 45, 49 - 54, 66, 67, 71, 72, 76, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simons as applied to claims 9, 30, 36, 41, 48, 63, 69, and 74 above, and further in view of Douglas et al. (USPN 6,183,489). Simons is directed to an arrangement for performing measurements from blood samples, but does not teach obtaining measurement results from interstitial fluid. Douglas et al. teach that disposable needle/microneedle sampling arrangements, like that of Simons, can also be used to sample interstitial fluid, which has the advantage of not having interference from red blood cells and not requiring hematocrit adjustment to the calculations (column 3, lines 27 - 37). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Simons to sample and analyze interstitial fluids, as taught by Douglas et al., since this removes

interference from red blood cells and eliminates the need to adjust for hematocrit in the measurement.

12. Claims 23 - 29 and 58 - 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simons in view of Douglas et al. for the reasons given in paragraphs 9 and 11 above.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 9 - 12, 15 - 17, 23, 24, 27, 30, 32 - 36, 38 - 41, 43, - 45, 47, and 74 - 78 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 78 - 82, 87, and 90 - 94 of U.S. Patent No. 6,923,764. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are broader than those of the

patent. Thus, any apparatus or method meeting the limitations of the patent would necessarily meet those of the instant application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571/272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768